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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DI CICCO, JOHN R	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,163	JUN, MYONG-KI	
	Examiner	Art Unit	
	John R. Di Cicco	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/17/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,29-31,33 and 34* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 27 are vague and indefinite because "relatively low" is unclear. One would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 22, 26, 27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US 6,514,251 B1) in view of Schwartz et al. (US 6,969,373 B2).

Regarding claims 21, 22, and 29, Ni et al. disclose an electrode for an electro-surgical operation device, comprising: a hollow electrode (49, Fig. 6) formed in a hollow tube shape extending from a closed tip (Fig. 6); a first non-insulation area formed to a predetermined length from the closed tip (col. 3, lines 44-46); a first insulation area formed on an outside surface of the hollow electrode beginning a predetermined length from the closed tip (as implied in col. 3, lines 44-46); a refrigerant tube (defined as 28 in Figs. 3 and 4), having a smaller diameter than a diameter of the hollow electrode, inserted into the hollow electrode (Fig. 6), the refrigerant tube configured to circulate pressurized (infusion pump, col. 4, lines 49-58) refrigerants so as to supply refrigerants (i.e. 0.9% saturated saline solution, col. 3, lines 16-21) from outside of a living body into the hollow electrode to cool living tissue in contact with at least one of the closed tip and the hollow electrode, and to discharge the heat-exchanged refrigerants (Fig. 8) out of the living body (Fig. 7), the pressurized refrigerants being a pressurized saline solution (infusion pump connected to a hypertonic solution, col. 4, lines 53-55); at least one first hole (or refrigerant discharging mechanism) formed on an outside surface of the first non-insulation area (shown near the tip in Fig. 6); the at least one first hole operable to externally discharge a portion of the circulated pressurized refrigerants into the living tissue in contact with at least one of the closed tip and the hollow electrode (as shown by the arrows running through the holes). Ni et al. further disclose the device further

comprising: a saline solution pipe (33, Fig. 3; and 38, Fig. 4) sheathing around the outside surface of the hollow electrode with a predetermined gap (33), and having a second non-insulation area at another predetermined length toward the closed tip (any non-insulation area on the electrode that has not been defined as the first non-insulation area) and a second insulation area on an outside surface of the saline solution pipe except the second non-insulation area (any insulation area not defined as the first insulation area); the saline solution pipe operable to infuse a saline solution having a relatively low pressure through the gap (infusion pump, col. 4, lines 53-55), and discharge the saline solution through at least one second hole (35) formed on an outside surface of the second non-insulation area (col. 4, lines 2-7). Ni et al. do not disclose flow control mechanism formed on the outside surface of the first non-insulation area.

Schwartz et al. teach a hollow catheter with a plurality of holes (66, Fig. 11) for injecting a solution into tissue in a predetermined cloud pattern (col. 4, lines 31-34). Schwartz et al. teach a flow control mechanism (76, Fig. 11) formed on the outside surface of the first non-insulation area, and operable to act as a discharge resistance to the pressurized refrigerants discharged from the at least one first hole, so as to control a flow of the pressurized refrigerants (col. 4, lines 47-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the flow control mechanism as taught by Schwartz et al. in the invention of Ni et al. in order to better control the cloud pattern of the refrigerant in the tissue to more effectively ablate the tissue.

Regarding claims 26 and 27, the claimed method is anticipated by the normal use of the device as disclosed by Ni et al. in view of Schwartz et al.

Regarding claim 30, Ni et al. in view of Schwartz et al. disclose the electrode of claim 21, wherein the closed tip of the hollow electrode (shown as 29 in Fig. 3 of Ni et al.) is a conductive spearhead (the closed tapered tip of Ni et al. is interpreted as a spearhead), and the hollow electrode and the spearhead are incorporated with each other (Figs. 3-7).

Regarding claim 31, Ni et al. in view of Schwartz et al. disclose the electrode of claim 29, wherein the flow control mechanism is a hollow tube sheathing around the outside surface of the first non-insulation area (Schwartz et al., Fig. 11), and having a third hole on the outside surface (Schwartz et al., element 84, Fig. 11) of the hollow tube, the flow control mechanism controlling a volume of the discharged pressurized refrigerants by alternately aligning the at least one first hole of the hollow electrode and the third hole of the hollow tube and operating as a discharge resistance to the pressurized refrigerants discharged from the at least one first hole (Schwartz et al., col. 17, lines 11-14; and Fig. 11).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view of Schwartz et al. as applied to claims 21 and 22 above and further in view of Hovda et al. (US 2003/0208194 A1).

Regarding claims 23 and 24, Ni et al. in view of Schwartz et al. disclose the electrode of claim 22, with the features described above, wherein the hollow electrode

and the saline solution pipe are conductive (Ni et al., col. 3, lines 44-46), further comprising a power source (65, Fig. 8) for providing RF electricity (col. 4, lines 56-58) and which is capable of being configured to apply different power to the hollow electrode and the saline solution pipe in the form of a bipolar configuration; but does not disclose an insulation member formed on the surface of the hollow electrode to prevent short circuiting. Hovda et al. teach an electrosurgical device comprising an electrode (104, Fig. 12A), and a second conducting member (112) which forms an annular gap (54) which defines a fluid path (83) for a conducting liquid (50, para. [0103]); an insulation member formed on the surface of the electrode (78) which would prevent short circuit of the saline solution supplied through the gap between the electrode and the saline solution pipe; and an insulation packing (102) provided between the electrode and the saline solution pipe (Fig. 12A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention as disclosed by Ni et al. in view of Schwartz et al. by including the saline solution pipe and insulation member as taught by Hovda et al. in order to ablate desired tissue in a bipolar configuration and to provide a pathway for electrical current flow between the active and return electrodes.

Claims 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view Schwartz et al. as applied to claims 21 and 29 above, and further in view of Brucker et al. (6,017,338).

Regarding claims 25 and 33, Ni et al. in view of Schwartz et al. disclose the electrode of claims 21 and 29, but do not disclose the flow control mechanism as a

porous metal sintered body layer. Brucker et al. teach an ablation catheter (22) with a central lumen (28) for introducing fluids into the catheter. The tip of the catheter (26) is made of sintered metal which contains a plurality of randomly formed through-passages and which permits a controlled flow of fluid from the catheter (col. 5, lines 30-34) and acts as a discharge resistance mechanism. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni et al. in view of Schwartz et al. by forming the flow control mechanism of porous sintered metal in order to obtain a desired discharged fluid profile in the tissue.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view Schwartz et al. as applied to claim 21 above, and further in view of Milder (5,281,215).

Regarding claim 34, Ni et al. in view of Schwartz et al. disclose the electrode of claim 21, but do not disclose the pressurized refrigerants having a pressure of approximately 700 to 1060 kPa. Milder teaches a cooling liquid under pressure, such as a chlorinated fluorocarbon at 150 pounds per square inch (col. 6, lines 35-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni et al. in view of Schwartz et al. by using a pressurized refrigerant as taught by Milder in order to cool the tip (col. 6, lines 65-66).

Allowable Subject Matter

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed November 15, 2007 have been fully considered but they are not persuasive.

Applicant argues Schwartz does not disclose a pressurized source. However, Schwartz provides a fluid through the device which is indicative that at least some pressure is applied to the source, even if the pressure is derived solely from gravity (e.g. a saline bag). Furthermore, applicant's claims do not distinguish the amount of pressure (or the type of pressure) used to cause fluid flow. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "high-pressure refrigerant") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that a pressurized fluid is not disclosed in the references and has thus amended the claims to reflect this. In response to applicant's arguments, Ni uses a fluid pump (col. 4, lines 53-55), and a fluid pump necessarily provides a pressure gradient to the fluid to cause it to flow through the device. In addition, Applicant's claims

fail to set forth any structure or pressure limitations that would distinguish over the pressure applied to the refrigerant by the fluid pump used in Ni.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6506189 B1; US 20040116921 A1; US 6814731 B2; US 6858025 B2; US 7156843 B2; US 7150744 B2; US 7077842 B1; US 6852120 B1; US 6818000 B2; US 6770070 B1; US 6723094 B1; US 6569159 B1; US 5688267 A; US 6605087 B2; US 6945969 B1; US 20060106338 A1; US 20060025752 A1; US 20050197633 A1; US 20030216726 A1; US 20050137579 A1; US 20020068930 A1; US 20030208194 A1; US 5425723 A; US 6352531 B1; US 5800408 A; US 20010021847 A1; US 6413255 B1; and US 6981382 B2.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John R. Di Cicco/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739